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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/071,016	02/07/2002	Micheal L. Gruenberg	24731-504B	9613

7590

03/24/2005

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EXAMINER

BELYAVSKIY, MICHAEL A

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 03/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/071,016

Applicant(s)

GRUENBERG, MICHEAL L.

Examiner

Michail A. Belyavskyi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 67-72 is/are pending in the application.
- 4a) Of the above claim(s) 70-72 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 67-69 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>08/29/02, 03/26/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 67-72 are pending.

Applicant's election without traverse of Group I, claims 67-69 in Response to Restriction Requirement, filed 01/10/05 is acknowledged.

Claims 70-72 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to nonelected inventions.

2. Claims 67-69 read on a composition of highly pure polyclonal Th1 cells obtained by activating the T cells with one or more mitogenic antibodies are under consideration in the instant application.

3. Applicant's amendment, filed 08/29/02 notes that an IDS was submitted with the prior application 09/957,194. However these citations have been crossed out as said references cited in said parent application cannot be found. Applicant is invited to resubmit such references to complete the instant file. The examiner apologizes for any inconvenience to applicant for having to resubmit such documents.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 67-69 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

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The specification does not enable one of skill in the art to practice the invention as claimed without undue experimentation.

It is noted that the instant Application and Application 10/246,647 both related to the method of producing a highly pure population of polyclonal Th1 memory cell for use in adoptive immunotherapy comprising the same method steps and ingredients. Dr. Gruenberg is the inventor of both applications.

In Applicant's petition by Dr. Gruenberg filed 07/07/2003 in Application 10/246,647 it is clearly stated "the specification detailed my ideas for a possible improvement to a cell therapy product, but **these ideas were never successfully reduced to practice** and in fact, preliminary data indicated that the method discussed in the specification did not elicit the expected beneficial results. The application does not disclose an actual invention." (see attached Petition).

Thus, Applicant has not provided sufficient guidance to enable one skill in the art to use claimed method of producing a highly pure population of polyclonal Th1 memory cell in manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement. *In re Fisher*, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute.

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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7. Claims 67 –69 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 35-47 , of copending Application No. 10/094,667 and claims 1, 3, 5, 7, 9-40, 46, 51-58 of copending Application 09/957,194 . Although the conflicting claims are not identical, they are not patentably distinct from each other because: (i) claims 35-47 of copending Application No. 10/094,667 recites a method of autologous cell therapy, comprising administering a composition of activated T cell, obtained by the method comprising collecting T cells from the subject and activating the T-cells at minimum 3 time at 2-4 days intervals with one or more mitogenic antibodies immobilized on microbeads. It is noted that claims 35-47 of copending Application No. 10/094,667 do not explicitly recited that activated T cells is polyclonal Th1 cells. However, said cells were obtained by the same method, using the same mitogenic antibodies as claimed thus inherently would be a polyclonal Th1 cells. Since the office does not have a laboratory to test the referenced T cells generated by the referenced method it is applicant's burden to show that the reference T cells obtained by the referenced method is not polyclonal Th1 cells as recited in the claims. (ii) claims 1, 3, 5, 7, 9-40, 46, 51-58 of copending Application 09/957,194 recites a method of producing a highly pure population of polyclonal Th1 cells obtained by the method steps comprising collecting T cells from the subject and activating the T-cells at minimum 3 time at 2-4 days intervals with one or more mitogenic antibodies immobilized on microbeads. It would be immediately obvious to a person of ordinary skill in the art that the referenced method would result in generating the same composition of highly pure polyclonal Th1 cells as claimed because both the copending Application 09/957,194 and the instant Application used the same method and ingredients to generate the same composition of highly pure polyclonal Th1 cells.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8. Claims 67- 69 directed to an invention not patentably distinct from claims 48-60 of commonly assigned US Application NO: 10/246,647. Specifically, claims 48-60 of commonly assigned US Application NO: 10/246,647 recites a method of autologous cell therapy, comprising administering a composition of activated T cell, obtained by the method comprising collecting T cells from the subject and activating the T-cells at minimum 3 time at 2-4 days intervals with one or more mitogenic antibodies immobilized on microbeads. It is noted that claims 48-60 of commonly assigned US Application NO: 10/246,647 do not explicitly recited that activated T cells is polyclonal Th1 cells. However, said cells were obtained by the same method, using the same mitogenic antibodies as claimed thus inherently would be a polyclonal Th1 cells. Since the office does not have a laboratory to test the referenced T cells generated by the referenced method it is applicant's burden to show that the reference T cells obtained by the referenced method is not polyclonal Th1 cells as recited in the claims.

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9. The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned US Application 10/246,647, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 67-69 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 48-60 of copending Application No. 10/246,647. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 48-60 of copending US Application NO: 10/246,647 recites a method of autologous cell therapy, comprising administering a composition of activated T cell, obtained by the method comprising collecting T cells from the subject and activating the T-cells at minimum 3 time at 2-4 days intervals with one or more mitogenic antibodies immobilized on microbeads. It is noted that claims 48-60 of copending US Application NO: 10/246,647 do not explicitly recited that activated T cells is polyclonal

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Th1 cells. However, said cells were obtained by the same method, using the same mitogenic antibodies as claimed thus inherently would be a polyclonal Th1 cells. Since the office does not have a laboratory to test the referenced T cells generated by the referenced method it is applicant's burden to show that the reference T cells obtained by the referenced method is not polyclonal Th1 cells as recited in the claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

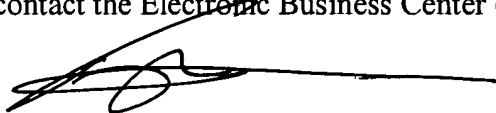
12. No claim is allowed.

13. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which Applicant may become aware in the specification.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskiy whose telephone number is 571/272-0840. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571/272-0841.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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March 15, 2005